Eric M. Fraser, 027241
Phillip W. Londen, 032488
OSBORN MALEDON, P.A.
2929 North Central Avenue, Suite 2000
Phoenix, Arizona 85012
(602) 640-9000
efraser@omlaw.com
plonden@omlaw.com

Wesley C. Achey (*pro hac vice application forthcoming*)
John D. Haynes (*pro hac vice application forthcoming*)
Matthew W. Howell (*pro hac vice application forthcoming*)
Katherine M. Donald (*pro hac vice application forthcoming*)
James Atkison (*pro hac vice application forthcoming*)
ALSTON & BIRD LLP
One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3424
(404) 881-7000
wes.achey@alston.com
john.Haynes@alston.com
matthew.howell@alston.com
katie.donald@alston.com
james.Atkison@alston.com

Attorneys for Plaintiff MiMedx Group, Inc.

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

MiMedx Group, Inc., Plaintiff, v. Surgenex, LLC, Defendant.	No. **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff MiMedx Group, Inc. ("MiMedx" or "Plaintiff") files this Complaint against Defendant Surgenex, LLC ("Surgenex" or "Defendant") and alleges as follows:

NATURE AND BASIS OF ACTION

1. This is a civil action for Surgenex's infringement of United States Patent Nos. 8,709,494 ("the '494 Patent"); 9,956,253 ("the '253 Patent"); 10,406,259 ("the '259 Patent"); 9,572,839 ("the '839 Patent"); 11,504,449 ("the '449 Patent"); 11,752,174 ("the '174 Patent"); 8,323,701 ("the '701 Patent"); 9,789,137 ("the '137 Patent"); and 10,874,697 ("the '697 Patent") (collectively, "Patents-in-Suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, 271, *et seq.*

2. MiMedx seeks, among other things, permanent injunctive relief, monetary damages, punitive damages, and recovery of MiMedx's costs and reasonable attorneys' fees incurred in connection with this action.

PARTIES

3. Plaintiff MiMedx is a corporation organized and existing under the laws of the State of Florida. MiMedx is registered to do business in the State of Georgia and maintains its headquarters and principal place of business at 1775 West Oak Commons Court, Marietta, Georgia 30062.

4. On information and belief, Defendant Surgenex is a corporation organized and existing under the laws of the State of Arizona with its principal place of business at 15444 North 76th Street, Suite C110, Scottsdale, Arizona 85260.

5. On information and belief, Surgenex is a biomaterials manufacturer and developer that is in the business of developing, marketing, distributing, offering to sell, and selling amnion- and chorion-based placental tissue graft products in the United States, including, but not limited to, PelloGraft®, ArdeoGraft®, SurGraft XT®, and SurGraft TL®.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this case arises under the United States Patent

Act, 35 U.S.C. §§ 100, 271, *et seq.*

7. This Court has general personal jurisdiction over Surgenex because Surgenex is incorporated and has its principal place of business in the State of Arizona.

8. This Court has specific personal jurisdiction over Surgenex because Surgenex transacts business within the State of Arizona, including, but not limited to, contracting to supply infringing placental tissue grafts in the State of Arizona, and otherwise engaging in acts of patent infringement within the State of Arizona by making, selling, and offering for sale placental tissue grafts that infringe the Patents-in-Suit.

9. Surgenex has purposefully and voluntarily placed its product(s), and/or caused its infringing product(s) to be placed, into the stream of commerce with the expectation that it will be purchased by consumers in this District. As such, Surgenex has established minimum contacts with the forum such that the exercise of jurisdiction over Surgenex would not offend traditional notions of fair play and substantial justice.

10. Surgenex also has continuous and systematic contacts within the State of Arizona. On information and belief, Surgenex: (1) has a corporate presence in the State of Arizona, including an office, real property, and personal property; (2) intentionally and actively markets and provides its placental tissue-based products, including PelloGraft®, ArdeoGraft®, SurGraft XT®, and SurGraft TL®, to residents of and businesses within the State of Arizona; (3) maintains numerous employees within the State of Arizona; and (4) enjoys substantial revenues from sales of its products and services in the State of Arizona.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400. In particular, Surgenex is incorporated in the State of Arizona and has its principal place of business in the State of Arizona.

BACKGROUND

I. MIMEDX AND ITS PRODUCTS

12. MiMedx develops, manufactures, and markets innovative and unique advanced wound interventions from human placental amniotic membranes.

13. MiMedx has been manufacturing and distributing products since at least 2008 and continues to expand its innovative product portfolio with new technologies.

14. In 2011, MiMedx acquired Surgical Biologics LLC, expanding MiMedx's business by adding allografts and other products processed from human amniotic membranes to MiMedx's existing medical device product lines. MiMedx has distributed over 3 million amniotic tissue grafts to patients in need thereof and achieved significant clinical outcomes in multiple therapeutic areas, including, but not limited to, the fields of ophthalmology, spinal surgery, chronic wound treatment, dental treatment, orthopedic surgery, sports medicine, and urology.

15. Over the years, MiMedx has spent millions of dollars researching and developing its proprietary placental tissue-based products and processes, and devotes significant financial resources each year in marketing its products and processes as well.

16. Because of the substantial expertise, investment of time, effort, and financial resources required to bring safe and efficacious bioactive healing products and processes to the market, MiMedx has sought and secured an extensive patent portfolio to protect its innovative tissue technology and products.

17. MiMedx has also conducted extensive clinical and laboratory tests on its tissue graft products, and is dedicated to providing safe, superior allografts.

18. Because of MiMedx's commitment to the development and testing of its products, MiMedx has become acclaimed for its novel placental tissue-based products. Indeed, MiMedx's products are some of the most well-known and well-respected in the industry.

19. MiMedx's initial product offering included EpiFix® and AmnioFix®, which are tissue grafts processed from human amniotic membrane that are derived from donated placentas using MiMedx's proprietary technology.

20. MiMedx processes the human amniotic membrane through a proprietary system to produce a safe and effective tissue product, which is commonly referred to as an "allograft." MiMedx's products are used in a vast number of clinical treatments,

including, but not limited to, advanced wound care, orthopedic/spine surgery, and sports medicine applications. In each of these areas, and many more, MiMedx's products act as a barrier and protect the wound bed to aid in the development of granulation tissue in acute and chronic closures, among other benefits.

II. THE PATENTS-IN-SUIT

21. MiMedx has an extensive patent portfolio, including the Patents-in-Suit, covering various placental tissue-based products.

22. On April 29, 2014, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 8,709,494, titled "Placental Tissue Grafts." The '494 Patent names John Daniel as an inventor.

23. The '494 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '494 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '494 Patent is attached as Exhibit A.

24. On May 1, 2018, the USPTO duly and legally issued United States Patent No. 9,956,253, titled "Placental Tissue Grafts." The '253 Patent names John Daniel as an inventor.

25. The '253 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '253 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '253 Patent is attached as Exhibit B.

26. On September 10, 2019, the USPTO duly and legally issued United States Patent No. 10,406,259, titled "Placental Tissue Grafts and Improved Methods of Preparing and Using the Same." The '259 Patent names John Daniel as an inventor.

27. The '259 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '259 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '259 Patent is attached as Exhibit C.

28. On February 21, 2017, the USPTO duly and legally issued United States Patent No. 9,572,839, titled "Placental Tissue Grafts and Methods of Preparing and Using the Same." The '839 Patent names John Daniel as an inventor.

29. The '839 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '839 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '839 Patent is attached as Exhibit D.

30. On November 22, 2022, the USPTO duly and legally issued United States Patent No. 11,504,449, titled "Placental Tissue Grafts and Methods of Preparing and Using the Same." The '449 Patent names John Daniel as an inventor.

31. The '449 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '449 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '449 Patent is attached as Exhibit E.

32. On September 12, 2023, the USPTO duly and legally issued United States Patent No. 11,752,174, titled "Placental Tissue Grafts and Improved Methods of Preparing and Using the Same." The '174 Patent names John Daniel, Randall Spencer, John Russo, and Robert Tofe as inventors.

33. The '174 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '174 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the '174 Patent is attached as Exhibit F.

34. On December 4, 2012, the USPTO duly and legally issued United States Patent No. 8,323,701, titled "Placental Tissue Grafts." The '701 Patent names John Daniel, Randall Spencer, John Russo, and Robert Tofe as inventors.

35. The '701 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the '701 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and

correct copy of the ’701 Patent is attached as Exhibit G.

36. On October 17, 2017, the USPTO duly and legally issued United States Patent No. 9,789,137, titled “Placental Tissue Grafts and Improved Methods of Preparing and Using the Same.” The ’137 Patent names John Daniel, Randall Spencer, John Russo, and Robert Tofe as inventors.

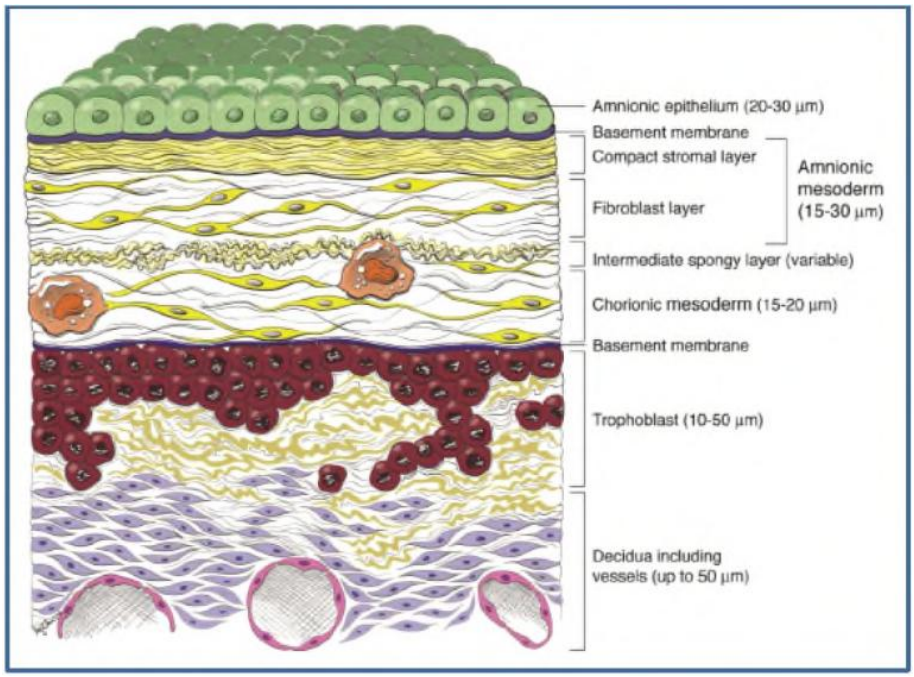
37. The ’137 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the ’137 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the ’137 Patent is attached as Exhibit H.

38. On December 29, 2020, the USPTO duly and legally issued United States Patent No. 10,874,697, titled “Placental Tissue Grafts and Improved Methods of Preparing and Using the Same.” The ’697 Patent names John Daniel, Randall Spencer, John Russo, and Robert Tofe as inventors.

39. The ’697 Patent has been assigned to MiMedx, and MiMedx has standing to sue and recover damages for infringement of the ’697 Patent and pursue any and all causes of actions and remedies, both legal and equitable, related thereto. A true and correct copy of the ’697 Patent is attached as Exhibit I.

A. BACKGROUND ON PATENTS-IN-SUIT

40. The Patents-in-Suit are directed to placental tissue grafts, *i.e.*, tissue grafts made from processed human placenta. The human placenta fetal membrane includes two primary membranes, the amniotic (amnion) and the chorionic (chorion) membranes, which are separated by a spongy (or intermediate) layer interface. Each of the amnion and chorion, *in utero*, is composed of various layers, as specified and depicted below (*see* Rebecca N. Baergen, *Manual of Pathology of the Human Placenta* at 104 (2d ed. 2011)):



41. The layers of human amnion include the amniotic epithelium (or the epithelial cellular layer), the basement membrane (or the basal lamina), the compact stromal layer, and the fibroblast layer.

42. The epithelial cellular layer is the innermost layer of the native placental amnion, closest to the fetus, and primarily consists of a single layer (or monolayer) of flat, or typically cuboidal, epithelial cells. The native amniotic epithelial cells are in contact with the underlying basement membrane.

43. The basement membrane is a thin layer, which is attached to and supports, and is therefore covered by, the epithelial cellular layer. The basement membrane is composed of a network of reticular fibers (a type of fibrous connective tissue). The basement membrane contains biological macromolecules, which includes, for example, collagen, laminin, and other proteoglycans.

44. The compact stromal layer lies beneath the basement membrane, consists of a complex network of connective tissue, and is somewhat (but not entirely) devoid of cells. The fibroblast layer of the amnion contains cells that are embedded in the "extracellular matrix" of the connective tissue, which is synthesized and maintained by the fibroblast cells in the fibroblast layer.

45. The spongy (or intermediate) layer resides between the amnion and the chorion in the natural placenta, and is comprised of a loosely arranged mesh of fine collagen fibrils embedded in a proteoglycan, mucin, and multi-protein rich complex. The spongy layer is loosely attached to the amnion and chorion via a fine network of anchor fibrils.

46. The cellular composition of native chorion is also extensively different from native amnion in that it is a tough fibrous and uneven layer comprised of trophoblastic cells and connective tissue. The chorion is also functionally distinct from the amnion. For example, the trophoblast cells have, among other things, endocrine functions, including production of several pregnancy related hormones. The chorion also has different physical properties than the amnion, ***e.g.***, chorion is generally three to four times thicker.

B. The ’494 Patent

47. The claims of the ’494 Patent are generally directed to placental tissue grafts derived from the amnion and chorion layers of the native human placenta. The ’494 Patent describes the “two primary layers” of the placenta, the amnion and chorion. (Ex. A, ’494 Patent, at 1:36-67.) The ’494 Patent describes the amnion as consisting of “epithelium cells, thin reticular fibers (basement membrane), a thick compact layer, and fibroblast layer.” (*Id.* at 1:40-43.)

48. The ’494 Patent also describes several benefits of amnion- and chorion-containing placental tissue grafts, such as, for example, providing a matrix for cellular migration/proliferation, providing a natural biological barrier, and promoting healing. (*Id.* at 1:49-55.) Moreover, the grafts taught by the ’494 Patent are easy to handle and can be stored at room temperature for extended periods of time without the need for refrigeration or freezing. (*Id.* at 1:55-58.)

49. Generally speaking, the ’494 Patent is directed to a method for preparing placental tissue grafts for medical use, which includes separating the amnion from the chorion of a placenta; washing and cleaning the separated membranes to remove blood

clots and extraneous tissue, such as the spongy (or intermediate) layer; and forming a laminated tissue graft by adhering those layers together, either via the dehydration process or via other means, such as adhesive. (*See, e.g.*, *id.* at Abstract, 2:14-24, 45-55, Fig. 1.)

50. In particular, the '494 Patent discloses "improved procedures for harvesting, processing, and preparing amnion and/or chorion tissue for later surgical grafting procedures." (*Id.* at 2:4-6.) The improved grafts "are comprised of single layers of amnion or chorion, multiple layers of amnion or chorion, or multiple layers of a combination of amnion and chorion." (*Id.* at 2:36-39.) Though some cells may be unavoidably removed as an indirect side effect of processing, the tissue claimed in the '494 Patent does not include substantial decellularization (*i.e.*, removal of 90% or more cells from the graft), but rather repeatedly emphasizes that processing of the tissue is to be conducted "gently" and "carefully." (*See, e.g.*, *id.* at 6:15-19, 6:32-34, 6:56-64.)

51. Once placental tissue is collected and screened (*see id.* at 5:5-54), tissue processing commences. The first main step taught by the '494 Patent is separation of the amnion from the chorion. (*Id.* at 6:32-55.)

52. After separation, the '494 Patent teaches that the amnion and chorion may be washed and cleaned to remove blood clots, extraneous tissue, and other contaminants. (*E.g.*, *id.* at 3:10-13, 6:56-7:9.) While a number of different methods to clean the amnion and chorion exist, the '494 Patent specifies that the placenta is preferably cleaned in a hyperisotonic solution, such as NaCl concentration in a range from 10% to 30%. (*Id.* at 3:1-3, 7:25-30.)

53. Through this washing and cleaning process, including through the removal of extraneous tissue and subsequent lamination, such as the spongy (or intermediate) layer, the grafts of the '494 Patent and related patents have characteristics that are markedly different from the characteristics of natural placental tissue.

54. In some, but not all, embodiments, the tissue graft may also be soaked in antibiotic solution, and subsequently rinsed to remove remnants of the antibiotic solution, which further cleans the tissue. (*Id.* at 3:4-9, 7:30-56.)

55. The ’494 Patent also teaches that a laminate may be formed by, for example, mounting layers of amnion and chorion on a drying fixture and dehydrating them together. (*Id.* at 3:33-39.)

C. The ’253 Patent

56. The ’253 Patent is in the same patent family as the ’494 Patent. Accordingly, it has substantially the same specification and disclosure as the ’494 Patent, generally directed to placental tissue grafts derived from the amnion and chorion layers of the native human placenta. This includes the gentle, careful cleaning of the tissue layers. (*See, e.g.*, Ex. B, ’253 Patent, at 6:20-23, 6:36-38, 6:62-7:3.)

D. The ’259 Patent

57. The ’259 Patent is in the same patent family as the ’494 Patent. Accordingly, it has substantially the same specification and disclosure as the ’494 Patent, generally directed to placental tissue grafts derived from the amnion and chorion layers of the native human placenta. Like the ’494 Patent, the ’259 Patent discloses that “[t]o the extent possible, oxygen is removed from the inner pouch before it is sealed” (Ex. C, ’259 Patent, at 9:66-67), and that “[i]n practice, it has been determined that the above allograft materials can be stored in room temperature conditions safely for at least five (5) years.” (*Id.* at 10:31-33.)

E. The ’839 Patent

58. The ’839 Patent is in the same patent family as the ’494 Patent. Accordingly, it has substantially the same specification and disclosure as the ’494 Patent, generally directed to placental tissue grafts derived from the amnion and chorion layers of the native human placenta. This includes descriptions of grafts comprising “multiple layers of . . . chorion” (*see, e.g.*, Ex. D, ’839 Patent, at 2:46), and the gentle, careful cleaning of the tissue layers (*see, e.g.*, *id.* at 6:21-24, 6:37-39, 6:63-7:4).

F. The ’449 Patent

59. The ’449 Patent is in the same patent family as the ’494 Patent. Accordingly, it has substantially the same specification and disclosure as the ’494 Patent,

generally directed to placental tissue grafts derived from the amnion and chorion layers of the native human placenta. Like the '494 Patent, the '449 Patent teaches grafts comprising "multiple layers of . . . chorion." (*See, e.g.*, Ex. E, '449 Patent, at 2:46.) The '449 Patent further explains that the membranes are treated with an antibiotic solution, rinsed, and then dehydrated (*see, e.g.*, *id.* at 7:19-20, 7:36-38, 7:65-66), and further teaches a shelf life of five years (*id.* at 10:27-29).

G. The '701 Patent

60. The '701 Patent is generally directed to placental tissue grafts derived from the amnion layer of the native human placenta, among other additional membranes, including, for example, chorion. (*See, e.g.*, Ex. G, '701 Patent, at 13:10-23.)

61. Like the '494 Patent, the '701 Patent describes amnion and chorion. (*See id.* at 1:25-37.) The processing steps between the '494 Patent and the '701 Patent are largely similar, and include separation, cleaning, dehydration, and lamination. (*See, e.g.*, *id.* at 3:6-26, 4:48-60, 5:1-23, 5:58-6:48, 6:60-8:3.) The '701 Patent also describes various benefits of and clinical procedures for the tissue grafts that practice the claimed invention. (*See, e.g.*, *id.* at 1:38-60, 8:41-52, 10:42-11:3, 11:16-39.)

62. As with the '494 Patent, through the washing and cleaning process, including the removal of extraneous tissue, such as the spongy (or intermediate) layer, and subsequent lamination, the grafts of the '701 Patent and related patents have characteristics that are markedly different from those of natural placental tissue.

63. The '701 Patent discloses graft embodiments "composed of at least one layer of amnion tissue where the epithelium layer has been substantially removed in order to expose the basement layer to host cells." (*See, e.g.*, *id.* at 1:64-67.) The '701 Patent teaches that by removing epithelial cells from an amnion layer to expose the basement membrane in certain embodiments, cells from the host can more readily interact with the cell-adhesion bio-active factors located on the top and within the basement membrane. (*See, e.g.*, *id.* at Abstract, 1:64-2:24, 5:25-31, 10:42-11:3.)

64. By exposing the basement membrane layer, the grafts of the '701 Patent

and related patents further have characteristics that are markedly different from the characteristics of natural placental tissue.

65. The ’701 Patent also discloses that it may be important to preserve an exposed fibroblast layer of the amniotic membrane. (*See, e.g.*, *id*. at 5:10-23.) The ’701 Patent teaches careful removal of residual blood and extraneous tissue, for example, with a blunt instrument, and cautions against aggressive cleaning to avoid removing the fibroblast layer. (*See, e.g.*, *id*. at 5:13-23.)

H. The ’174 Patent

66. The ’174 Patent is in the same patent family as the ’701 Patent. Accordingly, it has substantially the same specification and disclosure as the ’701 Patent (*see* ¶ 60, above), generally directed to placental tissue grafts derived from the amnion layer of the native human placenta, among other additional membranes, including the chorion. The ’174 Patent indicates that the placental tissue grafts may be modified with a small gauge needle or punch to comprise a plurality of holes. (*See, e.g.*, Ex. F, ’174 Patent, at 9:53-10:5, Fig. 10.)

67. By adding a plurality of holes, the grafts of the ’174 Patent and related patents have further characteristics that are markedly different from the characteristics of natural placental tissue.

I. The ’137 Patent

68. The ’137 Patent is in the same patent family as the ’701 Patent. Accordingly, it has substantially the same specification and disclosure as the ’701 Patent, generally directed to placental tissue grafts derived from the amnion layer of the native human placenta, among other additional membranes, including chorion. The ’137 Patent notes that the use of sutures is optional. (*See, e.g.*, Ex. H, ’137 Patent, at 11:38-39.)

J. The ’697 Patent

69. The ’697 Patent is in the same patent family as the ’701 Patent. Accordingly, it has substantially the same specification and disclosure as the ’701 Patent, generally directed to placental tissue grafts derived from the amnion layer of the native

human placenta, among other additional membranes, including chorion. The '697 Patent indicates that its grafts may be modified with a small gauge needle or punch to comprise a plurality of holes. (*See, e.g.*, Ex. I, '697 Patent, at 9:50-10:2, Fig. 10.)

III. SURGENEX

70. Surgenex manufactures, distributes, sells, and offers to sell placental tissue-based products, including, but not limited to, the PelloGraft®, ArdeoGraft®, SurGraft XT®, and SurGraft TL® products.

71. Surgenex describes itself on its website's "About" page as a "contract research and manufacturing organization specializing in human cellular and tissue-based products," and further states that it is "focused on the development and commercialization of placental tissue and musculoskeletal based implants."[1]

72. Surgenex's website also states that it has a 17,500 square foot on-site facility, including over 5,000 square feet of clean room space, for processing its allograft products. A screenshot from Surgenex's website is reproduced below.

Surgenex Processing Facility

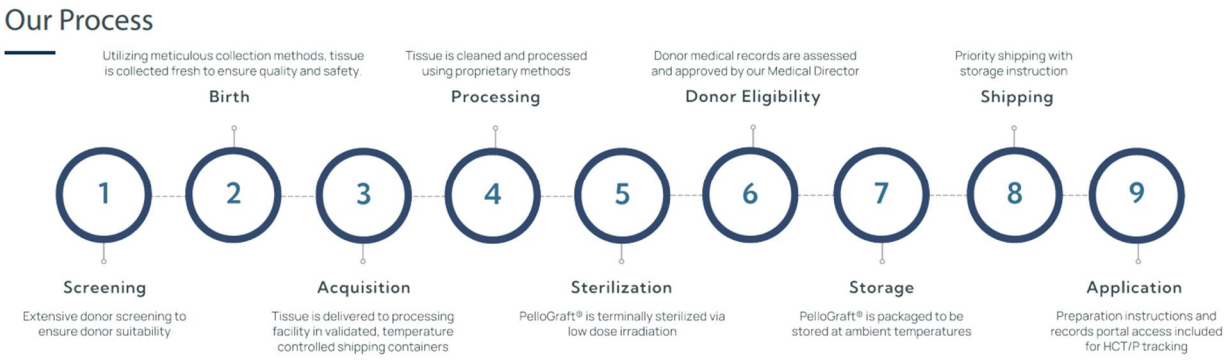
73. Surgenex's website also asserts that it "offer[s] a full suite of processing

[1] https://www.surgenex.com/about, last accessed Dec. 16, 2024.

capabilities to supply traditional birth tissue and musculoskeletal allografts through customized, innovative implants."

74. Surgenex manufactures, sells, and offers for sale numerous placental tissue products, in varying configurations, including placental amnion layer(s), chorion layer(s), and/or the intermediate layer.

75. Surgenex's entire process for obtaining donor tissue, preparing, storing, delivering, and using their products is summarized in the following figure, depicting nine distinct steps:



76. The above figure is taken from the PelloGraft® product flyer,[2] and an analogous figure is shown in the ArdeoGraft® product flyer.[3] No comparable flyer is available for the SurGraft XT® and SurGraft TL® products, but, on information and belief, the processes are substantially the same for those products.

77. Step 1 involves screening donors, including a risk assessment interview, review of medical records, and serological, microbiological, and infectious disease testing. Surgenex's website describes the screening process as follows:

---

[2] https://cdn.prod.website-files.com/60dc5ea6b948335b79027531/66ef14964318e4f0ca48955d_Pellograft%20Sell%20Sheet%20-%20Form%201.12.14%20Rev%202-compressed.pdf, last accessed Dec. 16, 2024

[3] https://cdn.prod.website-files.com/60dc5ea6b948335b79027531/6720f1e0e9faeb6235bb0610_ArdeoGraft%20Sell%20Sheet%20-%20Form%201.12.29%20REV%201.pdf, last accessed Dec. 16, 2024.

> Independent, contracted tissue recovery agencies follow strict protocols in accordance with FDA regulations and AATB standards. Serological and microbiological testing is performed at an independent, CLIA certified, FDA registered laboratory against standards that exceed the requirements of the FDA and AATB. Final donor eligibility is determined by a licensed medical director following review of all infectious disease testing, the uniform donor risk assessment interview and all relevant medical records.

78. Surgenex's Product Digital Catalog[4] states that this screening process includes testing for hepatitis B and C, HIV, HTLV 1, syphilis, HBV, HCV, West Nile virus, and other microbes. Steps 2 and 3 involve birth and acquisition of the placental tissue.

79. Once the recovery agencies collect and deliver the placental tissue to Surgenex, in Step 4, processing takes place in the in-house facility:

> Tissue is shaped using specially designed clean room equipment and subjected to a proprietary series of processing steps to effectively clean and disinfect allografts without the use of harsh chemicals.

Surgenex Product Digital Catalog

80. Surgenex states on its website that its processing includes "[m]inimal manipulation to retain the native biomechanical structure of host tissue" and "[e]xhaustive post-processing rinsing to effectively eliminate processing reagents."

81. Accordingly, on information and belief, Surgenex retains the amniotic epithelial layer in its amnion-containing products.

82. Next, according to Surgenex's website, the tissue is "lyophilized or dehydrated and subjected to post processing evaluation prior to final packaging."

---

[4] https://cdn.prod.website-files.com/60dc5ea6b948335b79027531/67197edde45fd62a07652c52_Form%201.12.19%20-%20Surgenex%20Product%20Digital%20Catalog%20REV4.pdf, last accessed Dec. 16, 2024.

83. After these processing steps, Step 5 is sterilization via irradiation. Surgenex's website explains the process as follows:

> Following processing, allografts are subjected to terminal sterilization via low dose irradiation to a sterility assurance level of 10^{-6}.

84. In Step 6, the information obtained in Step 1 is reviewed again by Surgenex prior to releasing the tissue for distribution.

85. Step 7 of the Surgenex process is storage. The below figure indicates that the PelloGraft® product may be stored at ambient temperature (*i.e.*, room temperature):

PelloGraft® is packaged to be stored at ambient temperatures

86. The PelloGraft® product flyer asserts that it has a five-year shelf life:

> **PelloGraft®** promotes optimal healing, serves as a protective barrier, and helps reduce complications in the healing process. It has a five-year shelf life.

87. The products are then shipped to a distributor or provider (Step 8), and include preparation instructions for application (Step 9).

88. The Surgenex Product Digital Catalog states that the PelloGraft®, ArdeoGraft®, SurGraft XT®, and SurGraft TL® products are suitable for wound care:

Table Of Contents

A. The PelloGraft® Product

89. Surgenex makes, sells, and/or offers to sell the PelloGraft® product in the United States in and this District.

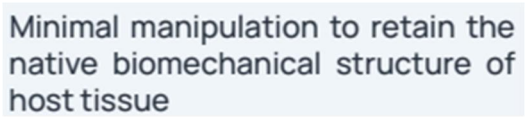
90. On information and belief, the PelloGraft® product is a placental tissue graft product comprising one layer of amnion and one layer of chorion. The PelloGraft® product flyer indicates that the product is a "dual-layer amnion/chorion derived placental allograft."

91. On information and belief, the PelloGraft® product is processed such that the native amnion layer is separated from the native chorion layer.

92. On information and belief, and based on how Surgenex describes

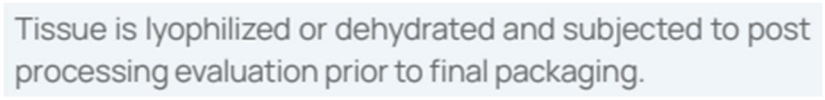
processing different "Full-Thickness" products,[5] the PelloGraft® product is processed such that each amnion layer and chorion layer is cleaned and washed separately, whereby blood and extraneous tissue is removed.

93. The PelloGraft® product is processed to retain certain cellular layers, including the epithelial cellular layer and the fibroblast cellular layer.



Surgenex Product Digital Catalog

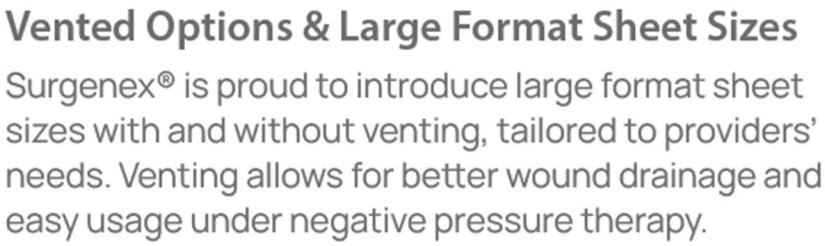
94. Surgenex's PelloGraft® placental tissue graft products are dehydrated.



Surgenex Product Digital Catalog

95. Surgenex's PelloGraft® placental tissue graft product comprises an amnion layer and a chorion layer and are laminated to make them suitable for their intended use, according to the PelloGraft® product website.[6] On information and belief, adjacent amnion and chorion layers in the PelloGraft® products are laminated directly to each other.

96. On information and belief, at least one version or iteration of the PelloGraft® product is "vented" to improve wound drainage, meaning that the product comprises a plurality of holes.



PelloGraft® Product Flyer

---

[5] https://www.surgenex.com/products/surgraft-ft, last accessed Dec. 16, 2024.

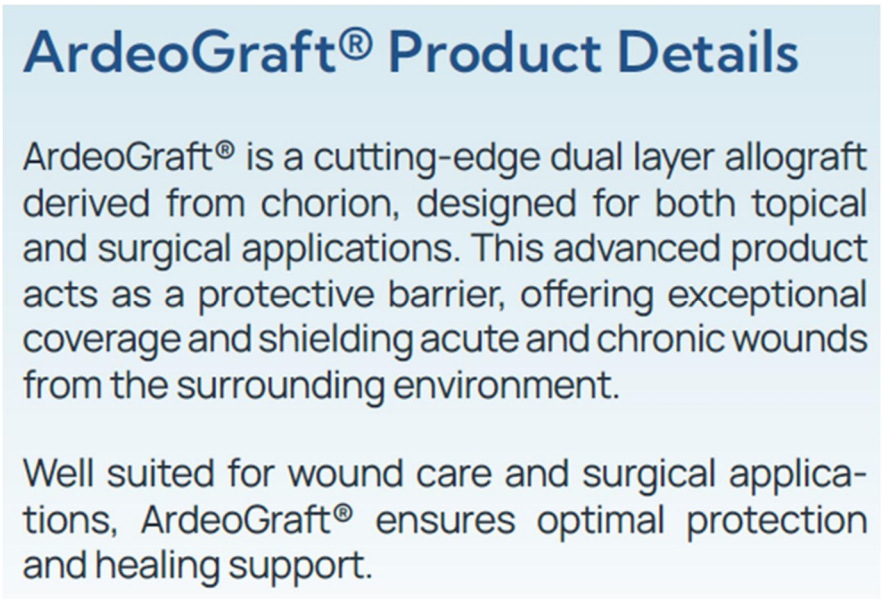
[6] https://www.surgenex.com/products/pellograft, last accessed Dec. 16, 2024.

97. Surgenex offers non-vented versions of PelloGraft® in five different sizes, and vented versions of PelloGraft® in three different sizes, as shown on its PelloGraft® product flyer:

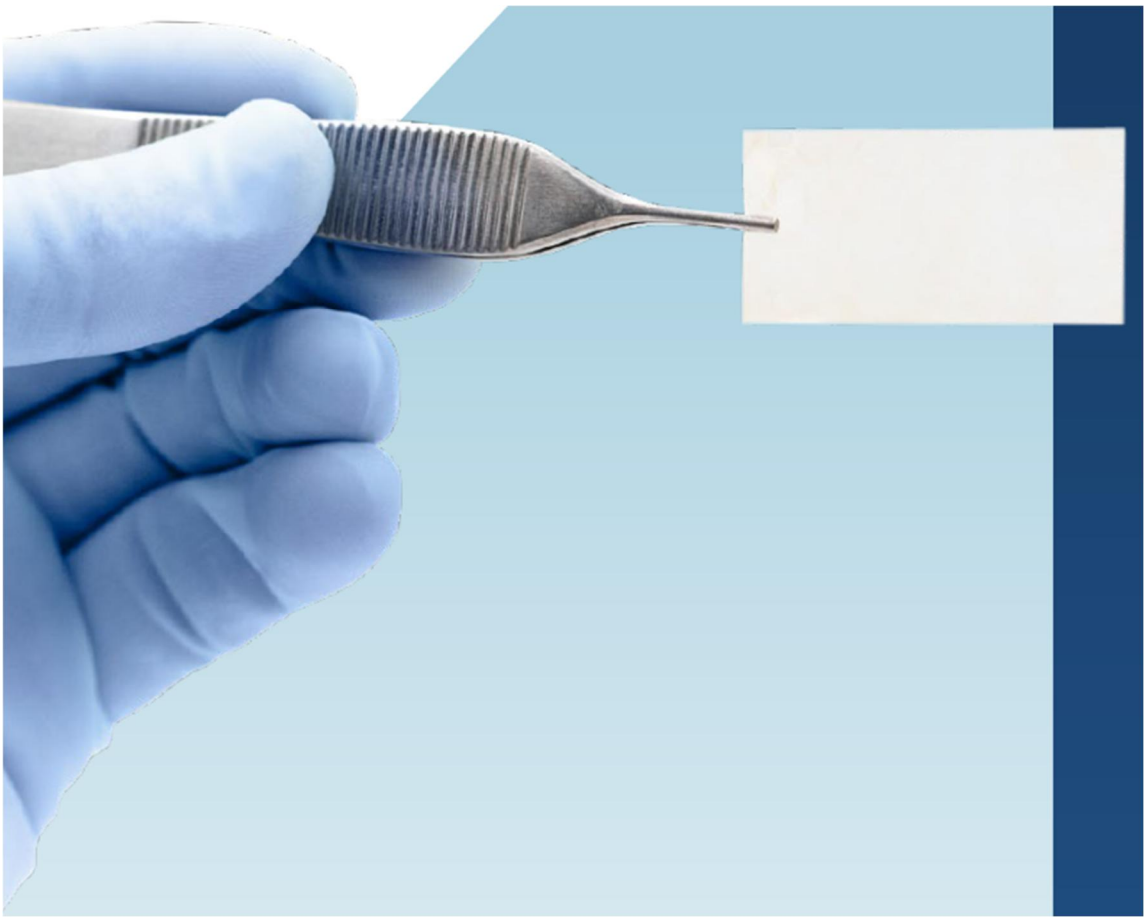
B. The ArdeoGraft® Product

98. On information and belief, Surgenex makes, sells, and/or offers to sell the ArdeoGraft® product in the United States in and this District.

99. On information and belief, the ArdeoGraft® product is a placental tissue graft product comprising two layers of chorion, according to the ArdeoGraft® product flyer. The ArdeoGraft® product flyer states that it is a "dual layer allograft derived from chorion" and a "Dual Layer Chorion" product:



ArdeoGraft® product flyer



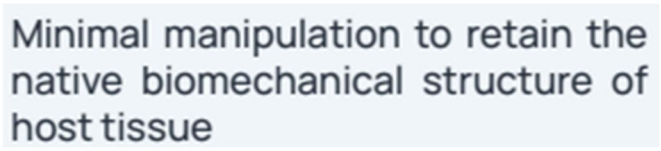
ArdeoGraft® Product Flyer

100. On information and belief, the ArdeoGraft® product is processed such that the native chorion layers of the graft are separated from their respective native amnion

layers.

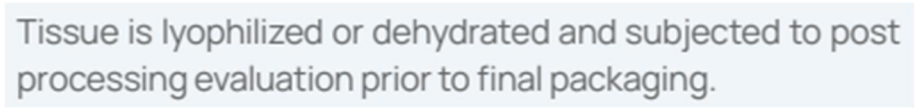
101. On information and belief, and based on how Surgenex describes processing different "Full-Thickness" products, the ArdeoGraft® product is processed such that each chorion layer is cleaned and washed separately, whereby blood and extraneous tissue are removed.

102. The ArdeoGraft® product is processed to avoid removal of cells.



Surgenex Product Digital Catalog

103. Surgenex's ArdeoGraft® placental tissue graft products are dehydrated.



Surgenex Product Digital Catalog

104. Surgenex's ArdeoGraft® placental tissue graft product comprises two chorion layers, and are laminated to make them suitable for their intended use, according to the ArdeoGraft® product website.[7] On information and belief, the adjacent chorion layers are laminated directly to each other.

105. Surgenex offers ArdeoGraft® in eleven different sizes, as shown on the ArdeoGraft® product website.

C. The SurGraft XT® Product

106. On information and belief, Surgenex makes, sells, and/or offers to sell the SurGraft XT® product in the United States in and this District.

107. On information and belief, the SurGraft XT® product is a placental tissue graft product comprising two layers of amnion. The SurGraft XT® product website[8] states that it is a "dual layer allograft sourced from amnion" and a "Dual Layer Amnion"

---

[7] https://www.surgenex.com/products/ardeograft, last accessed Dec. 16, 2024.

[8] https://www.surgenex.com/products/surgraft-xt, last accessed Dec. 16, 2024.

product:

SurGraft XT® Product Website

SurGraft XT® Product Website

108. On information and belief, the SurGraft XT® product is processed such that the native amnion layers of the graft are separated from their respective native chorion layers.

109. On information and belief, and based on how Surgenex describes processing different "Full-Thickness" products, the SurGraft XT® product is processed such that each amnion layer is cleaned and washed separately, whereby blood and extraneous tissue are removed.

110. On information and belief, the SurGraft XT® product is processed to retain certain cellular layers, including the epithelial cellular layer and the fibroblast cellular layer.

Minimal manipulation to retain the native biomechanical structure of host tissue

Surgenex Product Digital Catalog

111. Surgenex's SurGraft XT® placental tissue graft products are dehydrated.

Tissue is lyophilized or dehydrated and subjected to post processing evaluation prior to final packaging.

Surgenex Product Digital Catalog

112. Surgenex's SurGraft XT® placental tissue graft product comprises two amnion layers and are laminated to make them suitable for their intended use, according to the SurGraft XT® product website. On information and belief, the adjacent amnion layers are laminated directly to each other.

113. On information and belief, according to the SurGraft XT® product website, at least one version or iteration of the SurGraft XT® product is "vented" to improve wound drainage, meaning that the product comprises a plurality of holes.

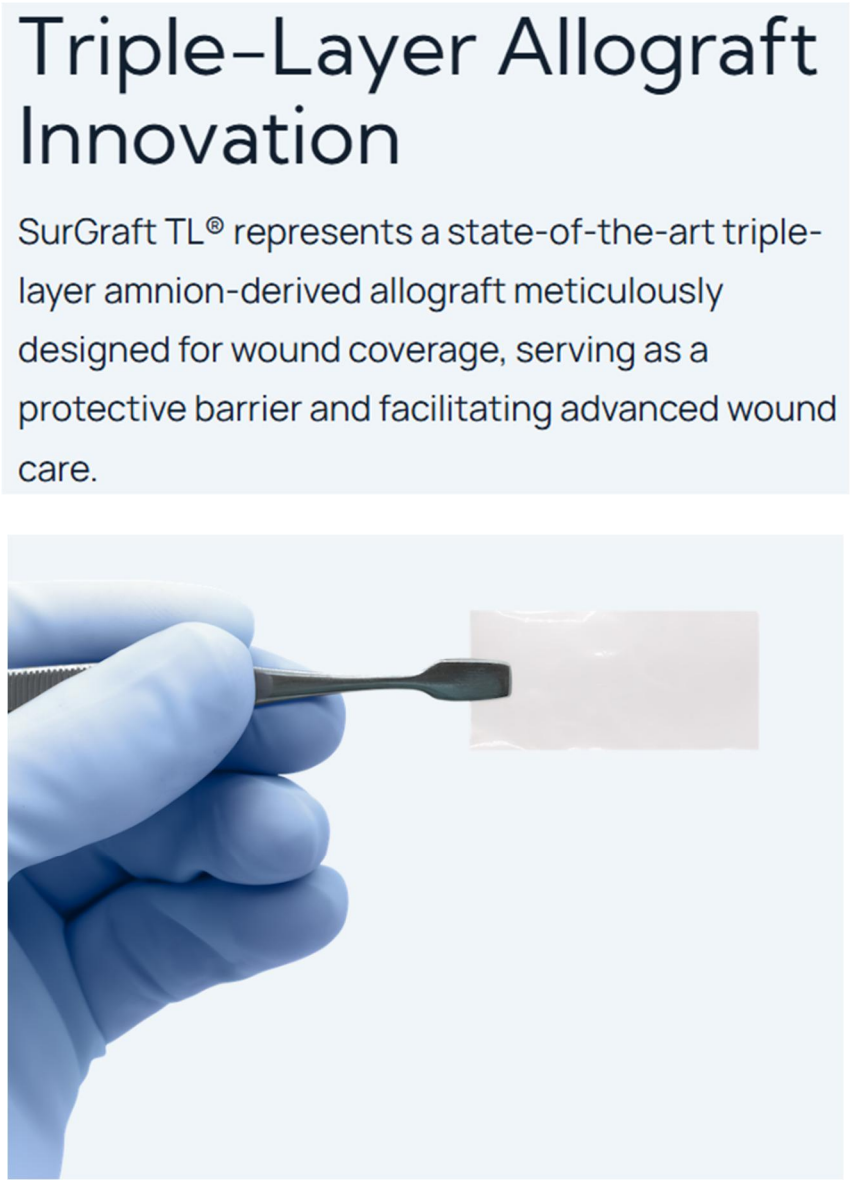
Surgenex® is proud to introduce large format sheet sizes with and without venting, tailored to providers' needs. Venting allows for better wound drainage and easy usage under negative pressure therapy.

SurGraft XT® Product Website

D. The SurGraft TL® Product

114. On information and belief, Surgenex makes, sells, and/or offers to sell the SurGraft TL® product in the United States in and this District.

115. On information and belief, the SurGraft TL® product is a placental tissue graft product comprising two layers of amnion (*i.e.*, having at least two layers of amnion). The SurGraft TL® product website[9] states that it is a "triple-layer amnion-derived allograft" and a "Triple Layer Amnion" product.

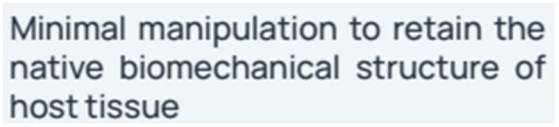


[9] https://www.surgenex.com/products/surgraft-tl, last accessed Dec. 16, 2024.

116. On information and belief, the SurGraft TL® product is processed such that the native amnion layers of the graft are separated from their respective native chorion layers.

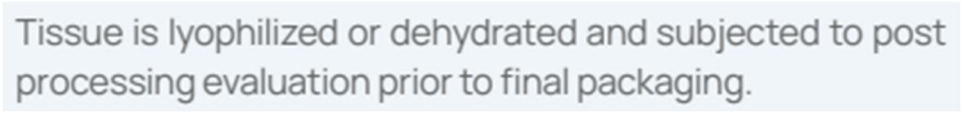
117. On information and belief, and based on how Surgenex describes processing different "Full-Thickness" products, the SurGraft TL® product is processed such that each amnion layer is cleaned and washed separately, whereby blood and extraneous tissue are removed.

118. The SurGraft TL® product is processed to retain certain cellular layers, including the epithelial cellular layer and the fibroblast cellular layer.



Surgenex Product Digital Catalog

119. Surgenex's SurGraft TL® placental tissue graft products are dehydrated.



Surgenex Product Digital Catalog

120. On information and belief, Surgenex's SurGraft TL® placental tissue graft product is laminated to make them suitable for their intended use. On information and belief, the adjacent amnion layers are laminated directly to each other.

E. Allegations Relating to All Surgenex Products

121. Surgenex has infringed and continues to infringe one or more claims of the Patents-in-Suit by manufacturing, using, selling, and/or offering for sale placental tissue-graft products in the United States and in this District that infringe one or more claims of each of the Patents-in-Suit including, but not limited to, Surgenex's PelloGraft®, ArdeoGraft®, SurGraft XT®, and SurGraft TL® placental tissue grafts.

122. Surgenex has been on actual notice of the Patents-in-Suit since at least of the filing of this lawsuit.

123. Additionally, on information and belief, Surgenex has had constructive

knowledge of the Patents-in-Suit at least by virtue of the identification of the Patents-in-Suit on the AmnioFix® and EpiFix® product labels, package information, and/or marketing materials by referencing www.mimedx.com/patents under the heading "Amniotic Membrane Allograft Product Lines."

124. On information and belief, Surgenex has acted and continues to act without a reasonable basis for believing that it would not be liable for infringing the Patents-in-Suit.

COUNT I

(INFRINGEMENT OF U.S. PATENT NO. 8,709,494)

125. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 124 of this Complaint, as though fully set forth herein.

126. MiMedx is the sole owner of the entire right, title, and interest in and to the '494 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

127. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '494 Patent by making, using, selling, and/or offering to sell within the United States at least the PelloGraft®, SurGraft XT®, and SurGraft TL® products, which infringe one or more claims of the '494 Patent in violation of 35 U.S.C. § 271.

128. Exemplary claim 9 of the '494 Patent recites:

> 9. A dehydrated, laminated, placental tissue graft which is a laminate comprising two or more separated and washed layers which layers are selected from amnion and/or chorion wherein the layers are directly laminated to each other and at least one of said layers is an amnion layer which retains an epithelial cellular layer.

129. As shown above, exemplary claim 9 covers a dehydrated, laminated, placental tissue graft comprising two or more layers selected from amnion and/or chorion directly laminated to each other, wherein at least one layer is an amnion layer which retains an epithelial cellular layer.

130. The PelloGraft® product infringes at least exemplary claim 9 of the '494 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) The layers are separated from each other during processing. (*See* ¶ 91, above.) The PelloGraft® product is also washed and cleaned during processing. (*See* ¶ 92, above.) Surgenex touts a cleaning process with "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, the PelloGraft® product's amnion layer retains the epithelial layer. (*See* ¶ 93, above.)

131. The SurGraft XT® product also infringes at least exemplary claim 9 of the '494 Patent, as SurGraft XT® comprises two layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) The layers are separated from chorion during processing. (*See* ¶ 108, above.) The SurGraft XT® product is also washed and cleaned during processing. (*See* ¶ 109, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the SurGraft XT® product's amnion layers retains the epithelial layer. (*See* ¶ 110, above.)

132. The SurGraft TL® product also infringes at least exemplary claim 9 of the '494 Patent, as SurGraft TL® comprises three layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 0, 119, above.) The layers are separated from chorion during processing. (*See* ¶ 116, above.) The SurGraft TL® product is also washed and cleaned during processing. (*See* ¶ 117, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the SurGraft TL® product's amnion layers retains the epithelial layer. (*See* ¶ 118, above.)

133. MiMedx has been damaged by Surgenex's past and continuing infringement of the '494 Patent in an amount to be determined at trial, and will continue to suffer damages in the future.

134. Surgenex's infringement of the '494 Patent has been willful. On

information and belief, Surgenex has known of MiMedx's patent rights, including the '494 Patent, but still deliberately and intentionally infringed that patent.

135. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '494 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

136. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

137. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '494 Patent.

COUNT II

(INFRINGEMENT OF U.S. PATENT NO. 9,956,253)

138. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 137 of this Complaint, as though fully set forth herein.

139. MiMedx is the sole owner of the entire right, title, and interest in and to the '253 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

140. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '253 Patent by making, using, selling, and/or offering to sell within the United States at least the PelloGraft® and SurGraft XT® products, which infringe one or more claims of the '253 Patent in violation of 35 U.S.C. § 271.

141. Exemplary claim 7 of the '253 Patent recites:

> 7. A dehydrated, laminated placental tissue graft which is a laminate consisting of two washed layers, wherein a first of said layers is an amnion layer which consists of an epithelial cellular layer, a basement membrane, a compact layer, and a fibroblast cellular layer, and a second of said layers is (i) amnion that consists of an epithelial cellular layer, a basement membrane, and a compact layer; (ii) amnion that consists of an epithelial cellular layer, a basement membrane, a compact layer, and a fibroblast cellular layer; or (iii) chorion, wherein the first and second layers are dehydrated and laminated to each other; and wherein the layers were separated prior to being laminated to each other.

142. As shown above, exemplary claim 7 covers a dehydrated, laminated, placental tissue graft comprising two layers directly laminated to each other, wherein the first layer is an amnion layer retaining its epithelial and fibroblast layers, and the second layer is an amnion layer retaining its epithelial layer, or a chorion layer.

143. The PelloGraft® product infringes at least exemplary claim 7 of the ’253 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) The layers are separated from each other during processing. (*See* ¶ 91, above.) The PelloGraft® product is also washed and cleaned during processing. (*See* ¶ 92, above.) Surgenex touts a cleaning process, including “[m]inimal manipulation to retain the native biomechanical structure of host tissue.” Thus, on information and belief, the PelloGraft® product’s amnion layer retains the epithelial layer. (*See* ¶ 93, above.)

144. The SurGraft XT® product also infringes at least exemplary claim 7 of the ’253 Patent, as SurGraft XT® comprises two layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) The layers are separated from chorion during processing. (*See* ¶ 108, above.) The SurGraft XT® product is also washed and cleaned during processing. (*See* ¶ 109, above.) Surgenex touts a cleaning process, including “[m]inimal manipulation to retain the native biomechanical structure of host tissue.” Thus, on information and belief, the SurGraft XT® product’s amnion layers retains the epithelial layer. (*See* ¶ 110, above.)

145. MiMedx has been damaged by Surgenex’s past and continuing

infringement of the ’253 Patent in an amount to be determined at trial.

146. Surgenex’s infringement of the ’253 Patent has been willful. On information and belief, Surgenex has known of MiMedx’s patent rights, including the ’494 Patent, but still deliberately and intentionally infringed that patent.

147. MiMedx has been and continues to be irreparably injured by Surgenex’s past and continuing infringement of the ’253 Patent, and Surgenex’s infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

148. MiMedx is entitled to monetary damages from Surgenex’s unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

149. Surgenex’s wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the ’253 Patent.

COUNT III

(INFRINGEMENT OF U.S. PATENT NO. 10,406,259)

150. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 149 of this Complaint, as though fully set forth herein.

151. MiMedx is the sole owner of the entire right, title, and interest in and to the ’259 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

152. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the ’259 Patent by making, using, selling, and/or offering to sell within the United States at least the PelloGraft®, SurGraft XT®, and SurGraft TL® products, which infringe one or more claims of the ’259 Patent

in violation of 35 U.S.C. § 271.

153. Exemplary claim 1 of the ’259 Patent recites:

> 1. A package comprising a sealed, deoxygenated container, said sealed, deoxygenated container comprising a dehydrated placental tissue graft, wherein said graft has a shelf-life of at least 5 years when stored in said container at room temperature; wherein said graft comprises a first layer which is a separated and washed amnion layer which comprises an epithelial cell layer, and a second layer which is a separated and washed amnion or chorion layer, and wherein the first and second layers are directly laminated to each other.

154. As shown above, exemplary claim 1 covers a package comprising a sealed, deoxygenated container comprising a dehydrated, laminated, placental tissue graft comprising a first layer, which is a separated and washed amnion layer, and a second layer, which is a separated and washed amnion or chorion layer, wherein the first and second layers are directly laminated to each other. The graft may comprise additional layers, and has a shelf-life of at least 5 years when stored in the container at room temperature.

155. The PelloGraft® product infringes at least exemplary claim 1 of the ’259 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) The layers are separated from each other during processing. (*See* ¶ 91, above.) The PelloGraft® product is also washed and cleaned during processing. (*See* ¶ 92, above.) The PelloGraft® product is described as having a five-year shelf life at ambient temperature (*See* ¶¶ 85-86, above); on information and belief, this would require storing the product in a sealed, deoxygenated container. Surgenex touts a cleaning process, including “[m]inimal manipulation to retain the native biomechanical structure of host tissue.” Thus, on information and belief, the PelloGraft® product’s amnion layer retains the epithelial layer. (*See* ¶ 93, above.)

156. The SurGraft XT® product also infringes at least exemplary claim 1 of the ’259 Patent, as SurGraft XT® comprises two layers of amnion which are directly

laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) The layers are separated from chorion during processing. (*See* ¶ 108, above.) The SurGraft XT® product is also washed and cleaned during processing. (*See* ¶ 109, above.) On information and belief, the packaging and shelf-life characteristics of SurGraft XT® would be the same as for the PelloGraft® product, as discussed above. (*See* ¶ 155, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the SurGraft XT® product's amnion layers retains the epithelial layer. (*See* ¶ 110, above.)

157. The SurGraft TL® product also infringes at least exemplary claim 1 of the '259 Patent, as SurGraft TL® comprises three layers of amnion, which are directly laminated to each other and are dehydrated. (*See* ¶¶ 0, 119, above.) The layers are separated from chorion during processing. (*See* ¶ 116, above.) The SurGraft TL® product is also washed and cleaned during processing. (*See* ¶ 117, above.) On information and belief, the packaging and shelf-life characteristics of SurGraft TL® would be the same as for the PelloGraft® product, as discussed above. (*See* ¶ 155, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the SurGraft TL® product's amnion layers retains the epithelial layer. (*See* ¶ 118, above.)

158. MiMedx has been damaged by Surgenex's past and continuing infringement of the '259 Patent in an amount to be determined at trial.

159. Surgenex's infringement of the '259 Patent has been willful. On information and belief, Surgenex has known of MiMedx's patent rights, including the '494 Patent, but still deliberately and intentionally infringed that patent.

160. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '259 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

161. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for

such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

162. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '253 Patent.

COUNT IV

(INFRINGEMENT OF U.S. PATENT NO. 9,572,839)

163. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 162 of this Complaint, as though fully set forth herein.

164. MiMedx is the sole owner of the entire right, title, and interest in and to the '839 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

165. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '839 Patent by making, using, selling, and/or offering to sell within the United States at least the ArdeoGraft® product, which infringes one or more claims of the '839 Patent in violation of 35 U.S.C. § 271.

166. Exemplary claim 1 of the '839 Patent recites:

> 1. A laminated placental tissue graft consisting of a first chorion tissue layer and a second chorion tissue layer which is laminated to said first chorion tissue layer, wherein at least one of the chorion tissue layers is not decellularized, and wherein said tissue graft is dehydrated.

167. As shown above, exemplary claim 1 covers a package comprising a sealed, deoxygenated container comprising a dehydrated, laminated, placental tissue graft comprising a first chorion tissue layer and a second chorion tissue layer laminated to the first layer, wherein at least one layer is not decellularized, wherein the first and second layers are directly laminated to each other.

168. The ArdeoGraft® product infringes at least exemplary claim 1 of the '839 Patent, as ArdeoGraft® comprises two layers of chorion that are laminated to each other and are dehydrated. (*See* ¶¶ 99 and 102, above.) The ArdeoGraft® product is also washed and cleaned during processing. (*See* ¶ 101, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the ArdeoGraft® product's chorion layers would not be decellularized. (*See* ¶ 102, above.)

169. MiMedx has been damaged by Surgenex's past and continuing infringement of the '839 Patent in an amount to be determined at trial.

170. Surgenex's infringement of the '839 Patent has been willful. On information and belief, Surgenex has known of MiMedx's patent rights, including the '494 Patent, but still deliberately and intentionally infringed that patent.

171. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '839 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

172. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

173. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '839 Patent.

COUNT V

(INFRINGEMENT OF U.S. PATENT NO. 11,504,449)

174. MiMedx repeats and incorporates by reference each and every allegation of

Paragraphs 1 through 173 of this Complaint, as though fully set forth herein.

175. MiMedx is the sole owner of the entire right, title, and interest in and to the '449 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

176. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 Patent by making, using, selling, and/or offering to sell within the United States at least the ArdeoGraft® product, which infringes one or more claims of the '449 Patent in violation of 35 U.S.C. § 271.

177. Exemplary claim 1 of the '449 Patent recites:

> 1. A package comprising a sealed, deoxygenated container, said sealed, deoxygenated container comprising a dehydrated, laminated placental tissue graft comprising a first chorion tissue layer and a second chorion tissue layer which is laminated to said first chorion tissue layer, wherein at least one of the chorion tissue layers is not decellularized, wherein said laminated placental tissue graft has been contacted with an antibiotic prior to being dehydrated; and wherein said graft has a shelf-life of at least 5 years when stored in said container at room temperature.

178. As shown above, exemplary claim 1 covers a package comprising a sealed, deoxygenated container comprising a dehydrated, laminated, placental tissue graft comprising a first chorion tissue layer and a second chorion tissue layer laminated to the first layer, wherein at least one layer is not decellularized, wherein the first and second layers are directly laminated to each other. The graft may comprise additional layers, and has a shelf-life of at least 5 years when stored in the container at room temperature.

179. The ArdeoGraft® product infringes at least exemplary claim 1 of the '449 Patent, as ArdeoGraft® comprises two layers of chorion that are laminated to each other and are dehydrated. (*See* ¶¶ 99 and 102, above.) On information and belief, the packaging and shelf-life characteristics of ArdeoGraft® would be the same as for the PelloGraft® product, as discussed above. (*See* ¶ 154, above.) Surgenex touts a cleaning process, including "[m]inimal manipulation to retain the native biomechanical structure of host tissue." Thus, on information and belief, at least one of the ArdeoGraft® product's

chorion layers would not be decellularized. (*See* ¶ 102, above.)

180. MiMedx has been damaged by Surgenex's past and continuing infringement of the '449 Patent in an amount to be determined at trial.

181. Surgenex's infringement of the '449 Patent has been willful. On information and belief, Surgenex has known of MiMedx's patent rights, including the '494 Patent, but still deliberately and intentionally infringed that patent.

182. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '449 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

183. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

184. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '449 Patent.

COUNT VI

(INFRINGEMENT OF U.S. PATENT NO. 11,752,174)

185. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 184 of this Complaint, as though fully set forth herein.

186. MiMedx is the sole owner of the entire right, title, and interest in and to the '174 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

187. Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '174 Patent by making, using,

selling, and/or offering to sell within the United States at least the PelloGraft® and SurGraft XT® products, which infringe one or more claims of the '174 Patent in violation of 35 U.S.C. § 271.

188. Exemplary claim 1 of the '174 Patent recites:

> 1. A tissue graft comprising a first membrane comprising an amnion and at least one additional membrane laminated to the first membrane, wherein the amnion comprises a basement membrane, a compact layer, and a fibroblast layer, and the at least one additional membrane is adjacent to the fibroblast layer; wherein each additional membrane consists of amnion, chorion, allograft pericardium, allograft acellular dermis, amniotic membrane, Wharton's jelly, purified xenograft Type-1 collagen, biocellulose polymers or copolymers, biocompatible synthetic polymer or copolymer films, purified small intestinal submucosa, bladder acellular matrix, cadaveric fascia, or any combination thereof; and wherein said graft comprises a plurality of holes.

189. As shown above, exemplary claim 1 covers a dehydrated, laminated, placental tissue graft comprising an amnion layer comprising a basement membrane, a compact layer, and a layer, and at least one additional membrane adjacent to the amnion's fibroblast layer, wherein the graft comprises a plurality of holes.

190. The PelloGraft® product infringes at least exemplary claim 1 of the '174 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 88, 94, above.) On information and belief, in this alternative scenario a second membrane would be placed in contact with the first amnion's fibroblast layer. "Vented" versions of PelloGraft®, comprising a plurality of holes, are also available. (*See* ¶ 96, above.)

191. The SurGraft XT® product also infringes at least exemplary claim 1 of the '174 Patent, as SurGraft XT® comprises two layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) The SurGraft XT® product is also washed and cleaned during processing. (*See* ¶ 109, above.) On information and belief, in this alternative scenario a second amnion layer would be placed in contact with the first amnion's fibroblast layer. "Vented" versions of SurGraft XT®, comprising a plurality of holes, are also available. (*See* ¶ 113, above.)

192. MiMedx has been damaged by Surgenex's past and continuing infringement of the '174 Patent in an amount to be determined at trial.

193. Surgenex's infringement of the '174 Patent has been willful. On information and belief, Surgenex has known of MiMedx's patent rights, including the '494 Patent, but still deliberately and intentionally infringed that patent.

194. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '174 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

195. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

196. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '174 Patent.

COUNT VII

(INFRINGEMENT OF U.S. PATENT NO. 8,323,701)

197. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 196**Error! Reference source not found.** of this Complaint, as though fully set forth herein.

198. MiMedx is the sole owner of the entire right, title, and interest in and to the '701 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

199. To the extent Surgenex's manufacturing process substantially removes the amnion's epithelial layer, Surgenex has infringed and continues to infringe, either literally

or under the doctrine of equivalents, one or more claims of the '701 Patent by making, using, selling, and/or offering to sell within the United States at least the PelloGraft®, SurGraft XT®, and SurGraft TL® products, which infringe one or more claims of the '701 Patent in violation of 35 U.S.C. § 271.

200. Exemplary claim 1 of the '701 Patent recites:

> 1. A tissue graft consisting of: a first membrane comprising modified amnion wherein the modified amnion has a first side which is an exposed basement membrane and a second side which is an exposed jelly-like fibroblast cellular layer; and one or more additional membranes sequentially layered such that the first additional membrane is layered adjacent to the exposed fibroblast layer of the first membrane, wherein the at least one or more additional membranes is selected from the group consisting of amnion, chorion, allograft pericardium, allograft acellular dermis, amniotic membrane, Wharton's jelly, and combinations thereof.

201. As shown above, exemplary claim 1 covers a dehydrated, laminated, placental tissue graft comprising two or more layers selected from amnion and/or chorion directly laminated to each other, wherein at least one layer is an amnion layer which has an exposed basement membrane. In this alternative scenario, the PelloGraft® product infringes at least exemplary claim 1 of the '701 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) In this alternative scenario, on information and belief, the amnion layer would have an exposed fibroblast layer.

202. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the SurGraft XT® product also infringes at least exemplary claim 1 of the '701 Patent, as SurGraft XT® comprises two layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) In this alternative scenario, on information and belief, at least one amnion layer would have an exposed fibroblast layer.

203. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the SurGraft TL® product also infringes at least exemplary claim 1 of the '701 Patent, as SurGraft TL® comprises three layers of amnion, which are

directly laminated to each other and are dehydrated. (*See* ¶¶ 0, 119, above.) In this alternative scenario, on information and belief, at least one amnion layer would have an exposed fibroblast layer.

204. MiMedx has been damaged by Surgenex's past and continuing infringement of the '701 Patent in an amount to be determined at trial.

205. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '701 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

206. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

207. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '701 Patent.

COUNT VIII

(INFRINGEMENT OF U.S. PATENT NO. 9,789,137)

208. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 207 of this Complaint, as though fully set forth herein.

209. MiMedx is the sole owner of the entire right, title, and interest in and to the '137 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

210. To the extent Surgenex's manufacturing process substantially removes the amnion's epithelial layer, Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '137 Patent by making,

using, selling, and/or offering to sell within the United States at least the PelloGraft®, SurGraft XT®, and SurGraft TL® products, which infringe one or more claims of the '137 Patent in violation of 35 U.S.C. § 271.

211. Exemplary claim 1 of the '137 Patent recites:

> 1. A dehydrated, laminated placental tissue graft which is a laminate comprising a washed amnion layer which has a first side which is an exposed basement membrane and a second side which is a fibroblast layer, and a second layer which is a washed amnion or a washed chorion, wherein said amnion layer and said second layer are dehydrated and laminated directly to each other; wherein said amnion layer and said second layer are not held in together with a suture.

212. As shown above, exemplary claim 1 covers a dehydrated, laminated, placental tissue graft comprising two or more layers selected from amnion and/or chorion directly laminated to each other, wherein at least one layer is an amnion layer which has an exposed basement membrane. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the PelloGraft® product infringes at least exemplary claim 1 of the '137 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) The PelloGraft® product is also washed and cleaned during processing. (*See* ¶ 92, above.) On information and belief, the layers of the PelloGraft® product, as sold, are not held in together by a suture. In this alternative scenario, on information and belief, the amnion layer would have a fibroblast layer.

213. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the SurGraft XT® product also infringes at least exemplary claim 1 of the '137 Patent, as SurGraft XT® comprises two layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) The SurGraft XT® product is also washed and cleaned during processing. (*See* ¶ 109, above.) On information and belief, the layers of the SurGraft XT® product, as sold, are not held in together by a suture. In this alternative scenario, on information and belief, at least one amnion layer would have a fibroblast layer.

214. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the SurGraft TL® product also infringes at least exemplary claim 1 of the '137 Patent, as SurGraft TL® comprises three layers of amnion which are directly laminated to each other and are dehydrated. (*See* ¶¶ 0, 119, above.) The SurGraft TL® product is also washed and cleaned during processing. (*See* ¶ 117, above.) On information and belief, the layers of the SurGraft TL® product, as sold, are not held in together by a suture. In this alternative scenario, on information and belief, at least one amnion layer would have a fibroblast layer.

215. MiMedx has been damaged by Surgenex's past and continuing infringement of the '137 Patent in an amount to be determined at trial.

216. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '137 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

217. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

218. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '137 Patent.

COUNT IX

(INFRINGEMENT OF U.S. PATENT NO. 10,874,697)

219. MiMedx repeats and incorporates by reference each and every allegation of Paragraphs 1 through 218 of this Complaint, as though fully set forth herein.

220. MiMedx is the sole owner of the entire right, title, and interest in and to the

'697 Patent, including the right to sue and recover, and pursue injunctive relief and all other available remedies for any and all infringements thereof.

221. To the extent Surgenex's manufacturing process substantially removes the amnion's epithelial layer, Surgenex has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the '697 Patent by making, using, selling, and/or offering to sell within the United States at least the PelloGraft® and SurGraft XT® products, which infringe one or more claims of the '697 Patent in violation of 35 U.S.C. § 271.

222. Exemplary claim 1 of the '697 Patent recites:

> 1. A tissue graft comprising a first membrane comprising an amnion and one or more additional membranes laminated to the first membrane, wherein the first membrane comprises an exposed basement membrane and a fibroblast layer, and the one or more additional membranes are adjacent to the fibroblast layer; wherein said graft comprises a plurality of holes.

223. As shown above, exemplary claim 1 covers a dehydrated, laminated, placental tissue graft comprising two or more layers selected from amnion and/or chorion directly laminated to each other, wherein at least one layer is an amnion layer which has an exposed basement membrane. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the PelloGraft® product infringes at least exemplary claim 1 of the '697 Patent, as PelloGraft® comprises a layer of amnion and a layer of chorion that are directly laminated to each other and are dehydrated. (*See* ¶¶ 90, 94, above.) On information and belief, in this alternative scenario, a second membrane would be placed in contact with the first amnion's fibroblast layer. "Vented" versions of PelloGraft®, comprising a plurality of holes, are also available. (*See* ¶ 96, above.) In this alternative scenario, on information and belief, the amnion layer would have an exposed fibroblast layer.

224. In this alternative scenario, if Surgenex's manufacturing process involves removal of the epithelial layer, the SurGraft XT® product also infringes at least exemplary claim 1 of the '697 Patent, as SurGraft XT® comprises two layers of amnion

which are directly laminated to each other and are dehydrated. (*See* ¶¶ 107, 111, above.) On information and belief, in this alternative scenario, a second amnion layer would be placed in contact with the first amnion's fibroblast layer. "Vented" versions of SurGraft XT®, comprising a plurality of holes, are also available. (*See* ¶ 113, above.) In this alternative scenario, on information and belief, at least one amnion layer would have a fibroblast layer.

225. MiMedx has been damaged by Surgenex's past and continuing infringement of the '697 Patent in an amount to be determined at trial.

226. MiMedx has been and continues to be irreparably injured by Surgenex's past and continuing infringement of the '697 Patent, and Surgenex's infringing activities will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

227. MiMedx is entitled to monetary damages from Surgenex's unauthorized infringement in an amount to be determined at trial. Surgenex is liable to MiMedx for such damages, which, by law, cannot be less than a reasonable royalty, together with interest and costs, as fixed by this Court under 35 U.S.C. § 284.

228. Surgenex's wrongful acts have damaged and will continue to damage MiMedx irreparably, and MiMedx has no adequate remedy at law for those wrongs and injuries. In addition to its actual damages, MiMedx is entitled to a permanent injunction that restrains and enjoins Surgenex and its agents, servants, and employees, and all persons acting thereunder, in concert with, or on its behalf, from infringing the '697 Patent.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for judgment against Defendant, granting Plaintiff the following relief:

A. Enter judgment that Defendant has infringed one or more claims of the Patents-in-Suit and that Defendant's infringement has been willful;

B. Award Plaintiff damages in an amount to be proven at trial that will adequately compensate MiMedx for Defendant's infringement, but under no

circumstances an amount less than a reasonable royalty, as authorized by 35 U.S.C. § 284;

C. Increase the damages sustained by Plaintiff up to three times the amount of MiMedx's actual damages, as authorized by 35 U.S.C. § 284;

D. Enjoin Surgenex, and all persons acting in concert with Surgenex, from the manufacture, use, sale, offer for sale, and/or importation of the accused products;

E. Award MiMedx its attorneys' fees and other expenses of litigation pursuant to 35 U.S.C. § 285;

F. Award MiMedx pre-judgment interest and costs pursuant to 35 U.S.C. § 284; and

G. Grant such other, different, and additional relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, MiMedx demands a trial by jury of all issues so triable.

DATED this 16th day of December, 2024.

OSBORN MALEDON, P.A.

By s/ Phillip W. Londen
Eric M. Fraser
Phillip W. Londen
2929 North Central Avenue, Suite 2000
Phoenix, Arizona 85012-2793

ALSTON & BIRD LLP
Wesley C. Achey (*pro hac vice forthcoming*)
John D. Haynes (*pro hac vice forthcoming*)
Matthew W. Howell (*pro hac vice forthcoming*)
Katherine M. Donald (*pro hac vice forthcoming*)
James Atkison (*pro hac vice forthcoming*)
One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3424

Attorneys for Plaintiff MiMedx Group, Inc.